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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/592,007	06/12/2000	Francis Tufaro	08582/009002	4193

7590 06/17/2002
Paul T Clark Esq
Clark & Elbing L L P
176 Federal Street
Boston, MA 02110

EXAMINER

WANG, ANDREW J

ART UNIT PAPER NUMBER

1635

DATE MAILED: 06/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/592,007

Applicant(s)

TUFARO ET AL.

Examiner

Andrew Wang

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-10,13-22 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-10,13-22 and 24-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Arguments and Amendments

1. Rejection of claims 1-8, 13, 14, 16, and 18-27 under 35 U.S.C. 102(b) as being anticipated by Dyer et al. is hereby withdrawn in view of applicants amendments file 3 April 2002.
2. Rejection of claims 1-5, 11-13, and 19-27 under 35 U.S.C. 102(b) as being anticipated by Wu et al (US Patent No. 5,728,399) is hereby withdrawn in view of applicants amendments filed 3 April 2002.
3. Rejection of claims 1-10 and 13-27 under 35 U.S.C. 103(a) as being unpatentable over Dyer et al. in view of Marasco et al. (US Patent No. 6,143,520) and Mislick et al. (US Patent No. 5,783,566) is hereby withdrawn in view of applicants amendments filed 3 April 2002.
4. Rejection of claims 3, 22, 23, and 25-27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn in view of applicants amendments filed 3 April 2002.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-3, 7-10, 13, 19, and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodgson et al.

Hodgson et al. disclose methods of infecting retroviral particles such as lentil viruses into tumor and muscle cells. Hodgson further teaches that said methods could be used in in vivo protocols to enhance gene therapy.

7. Claims 1-5, 7-10, and 13-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodgson et al. in view of Dyer et al., Marasco et al, and Mislick et al.

The invention of the above claims is drawn to a method of in vivo transfection comprising contacting a mammal with a viral vector (HIV or HSV) with a charged carrier such as dermatan sulfate or dextran sulfate.

Hodgson is relied upon as discussed above. Hodgson does not teach the various HIV strains nor the use of dextran sulfate or dermatan sulfate

Dyer et al. disclose the use of dextran sulfate to deliver an HSV vector comprising a gene to cells.

Marasco et al. teach the use of an HIV vector for transfection.

Mislick et al. teach the use of glycosaminoglycans, such as dermatan sulfate, and modified glycosaminoglycans, such as dextran sulfate to deliver DNA into cells.

It would have been obvious to one of ordinary skill in the art to use HSV or HIV vectors in the methods of Hodgson since both Dyer and Marasco teach that the vectors are capable of transfecting a variety of tissues. Moreover, it is known in the art that virions gain entry into a target cell by recognizing various receptors on the cell surface as demonstrated by Dyer et al. Moreover, the one would have expected that the use of dermatan sulfate or dextran sulfate to deliver a virus since the glycosaminoglycans are abundant on the cell surface as taught by Mislick et al. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in using dermatan or dextran sulfates to deliver HIV or HSV based vectors to a target cell.

Therefore, the invention of the above claims would have been prima facie obvious over Hodgson et al. in view of Dyer et al., Marasco et al. (US Patent No. 6,143,520), and Mislick et al. (US Patent No. 5,783,566) without evidence to the contrary.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

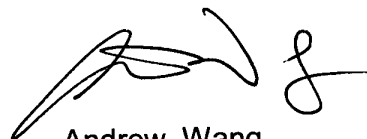
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Wang whose telephone number is 703-306-3217. The examiner can normally be reached on Monday thru Thursday, 6:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

AJW
June 14, 2002



Andrew Wang
Primary Examiner
Art Unit 1635